Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

This document is being resubmitted in its entirety in response to the Notice of Non-Compliant Amendment. The presence of text in claim 1 that was both underlined and marked with strikeout format has been deleted as the affected text did not appear in the original claim language. Thus, the basis asserted for non-compliance has been overcome. Please note that the appended exhibits submitted with the non-compliant amendment filed July 31, 2006, have already been entered and are not being re-submitted with this corrected document.

Claim 1 has been amended, claims 3-5 have been cancelled without prejudice, and new claims 10-21 have been added. Descriptive support for new claims 10 and 11 appears in the first full paragraph on page 30 and the third full paragraph on page 35, respectively; descriptive support for new claims 12-14 appears in the first full paragraph on page 34; and descriptive support for new claims 15 and 16 appears in the first full paragraph on page 30. New claim 17 finds descriptive support in original claim 3 (i.e., claim written in independent form), and new claims 17-21 find descriptive support in original claims 4 and 6-8, respectively. Claims 1, 2, and 6-21 are pending.

The objection to the specification is overcome by the above amendments. Although applicants disagree with the assertion made by the U.S. Patent and Trademark ("PTO"), the present claim language is clearly supported by the first full paragraph on page 30, along with the disclosure of the nucleic acid sequence of SEQ ID NO: 175 and the corresponding amino acid sequence of SEQ ID NO: 176.

The objections to claims 1 and 5 are overcome by the above amendments and should be withdrawn.

The rejection of claims 1-9 under 35 U.S.C. §112 (first paragraph) as lacking written descriptive support is respectfully traversed.

The burden of establishing that an application lacks adequate written descriptive support falls on the PTO. *See In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("[T]he PTO has the initial burden of presenting evidence or reasons why

persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."). Hence, the PTO must demonstrate *why* the disclosure is insufficient.

The Federal Circuit has clearly espoused that *per se* conclusions of written description violations cannot be founded upon the basis of genus size alone. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1326-27, 63 USPQ2d 1609, 1614-15 (Fed. Cir. 2002) (refusing to adopt position that three species as a matter of law cannot satisfy written description requirement for significantly larger genus). Thus, the PTO's conclusion cannot be based on genus size alone. But that is precisely what the PTO has done at pages 3-4 of the outstanding office action. Because the PTO's position is unsupported by law and unsupported by any facts other than genus size, applicants submit that the PTO's position cannot be sustained.

In contrast, applicants present Exhibits 1-3 (attached hereto) as evidence that the nucleic acid sequence of SEQ ID NO: 175 and the corresponding amino acid sequence of SEQ ID NO: 176 represent the claimed genus. Exhibit 1 is a presentation of Genbank accessions for *Bacillus* or *Geobacillus* (formerly *Bacillus*) *ssb* nucleic acids that are homologous to the nucleotide sequence of SEQ ID NO: 175. These *ssb* nucleic acids were identified by a protein-protein BLAST search of the Genbank database performed using the amino acid sequence of SEQ ID NO: 176 and the BLAST default settings. Homologous sequences were identified in *Geobacillus kaustophilus, Bacillus cereus*, *Bacillus anthracis*, *Bacillus thuringiensis*, *Bacillus weihenstephanensis*, *Bacillus subtilis*, *Bacillus licheniformis*, *Bacillus halodurans*, and *Bacillus clausii* (Exhibit 1). Based upon alignments performed using Align® for nucleic acids and ClustalW for amino acids (using the European Molecular Biology Laboratory server and its default settings), these homologs share between about 41 and about 66 percent identity at the nucleic acid level (Exhibit 2) and between about 54 and about 75 percent identity at the amino acid level (Exhibit 3). Thus, species of *ssb* molecules from organisms that belong to the biological classification *Bacillus* or *Geobacillus* clearly share similar structure and, therefore, function.

Applicants submit that the language recited in claims 1 and 9 is precisely the type of claim language that was acknowledged in *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) as being acceptable under the written description requirement. In *Eli Lilly*, the Federal Circuit addressed the validity of several claims of U.S. Patent No. 4,652,525 to Rutter et al. ("Rutter"), specifically those claims that recited the limitations 'vertebrate,' 'mammalian,' or 'human' cDNA for insulin. Rutter disclosed the

nucleotide and amino acid sequences of a rat cDNA encoding insulin, but merely described a general procedure for obtaining the human cDNA encoding insulin. *Id.* at 1567, 43 USPQ2d at 1405. The Federal Circuit found that the description of the rat cDNA did not provide adequate descriptive support for the narrow subgenus of 'human' cDNA (no species disclosed), the larger subgenus of 'mammalian' cDNA (only the one rat species disclosed), and the larger genus of 'vertebrate' cDNA (only the one rat species disclosed). *Id.* at 1567-68, 43 USPQ2d at 1405. The Federal Circuit did acknowledge, however, the district court's statement that the specification provided adequate written descriptive support for the subgenus of 'rat' cDNA encoding insulin. *Id.* at 1566.

Thus, functional language should be acceptable when the genus as claimed is sufficiently limited in scope (i.e., from *Bacillus*, including *Geobacillus*, or *Bacillus stearothermophilus*) and the specification describes one or more species within that genus. Claims 1 and 9 recite the same type of functional claim language that was identified as acceptable in *Eli Lilly* given the description of a single species by its nucleotide sequence. Thus, it should be evident that claims 1 and 9 (and claims dependent thereon) find written descriptive support in the present application.

It should be noted that the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶ 1, 'Written Description' Requirement," make explicitly clear that the description of a representative number of species does *not* require the description to be of such a nature that it would provide support for each species that the genus embraces. 66 Fed. Reg. 1099, 1106 (2001). Hence, the absence of sequences for the later-identified *ssb* and SSB protein homologs is irrelevant to the issue of whether the present specification provides adequate written descriptive support for their use in accordance with the present invention.

Moreover, the conclusion by the PTO is contrary to evidence submitted herewith by applicants. As demonstrated by Exhibits 1-3, one of ordinary skill in the art would have understood that applicants were in possession of the presently claimed invention at the time the present application was filed. This is so, because persons of skill in the art would have expected sufficiently related organisms from the genus *Bacillus* (and now *Geobacillus*) to possess homologous *ssb* nucleotide sequences or SSB proteins. Exhibits 1-3 confirm this expectation to have been reasonable.

In view of all of the foregoing, applicants submit that the rejection of claims 1-9 is improper and should be withdrawn.

The rejection of claims 1-9 under 35 U.S.C. §112 (first paragraph) for lack of enablement is respectfully traversed.

It is the position of the PTO that the specification does not provide sufficient guidance for making and using other SSB proteins within the scope of the claims. Applicants respectfully disagree.

The PTO is respectfully reminded that all that is needed is objective enablement of what is claimed. *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The present application provides the nucleotide sequence of *Bacillus stearothermophilus ssb* (e.g., SEQ ID NO: 175) and describes how one of ordinary skill can isolate homologs of the disclosed sequence (*see* page 41, line 9 to page 42, line 29; Example 12), express the SSB protein encoded by such homologous *ssb* sequences (*see* Example 23, purifying *Aquifex* SSB protein), and test the encoded SSB protein for activity (*see* Examples 26 and 30, using *Aquifex* SSB protein in assay). Thus, one of ordinary skill in the art would have been fully able to make and use DNA molecules and their encoded proteins within the scope of the presently claimed invention.

Moreover, with regard to method 3 for homolog identification, described at page 42, that is precisely the approach used to identify the *ssb* homologs shown in Exhibit 1 (i.e., from other *Bacillus* or *Geobacillus* organisms). For this reason, it should be apparent that the present application fully enables the production and use of other species of *Bacillus or Bacillus (*now *Geobacillus*) *stearothermophilus ssb* homologs.

In view of all of the foregoing, applicants submit that the rejection of claims 1-9 for lack of enablement is improper and should be withdrawn.

Because 1 is allowable for the reasons noted above, applicants further submit that new claims 10-16 also are allowable. Consistent with the PTO acknowledgments at pages 3-4 the outstanding office action, applicants further submit that that the specification provides written descriptive support for and enables the claimed DNA molecules that encode the SSB proteins including the amino acid sequence of SEQ ID NO: 176 (i.e., claims 17-21).

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: November 27, 2006

/Edwin V. Merkel/
Edwin V. Merkel
Registration No. 40,087

NIXON PEABODY LLP
Clinton Square, P.O. Box 31051
Rochester, New York 14603-1051
Telephone: (585) 263-1128
Facsimile: (585) 263-1600